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09/742,460	12/19/2000	Gary R. McLuen	NEI-00105	8839

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EXAMINER

QUAN, ELIZABETH S

ART UNIT PAPER NUMBER

1743

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/742,460

Applicant(s)

MCLUEN ET AL.

Examiner

Elizabeth Quan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 31-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 sheets.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second waste tube and the drain seal coupled to the waste tube for creating a seal between the first waste tube and one of the first and second drain must be shown or the feature(s) canceled from the claim(s). The drawings in corroboration with the specification do not show the drain seal in this specific configuration. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "520" has been used to designate mobile tube, waste tube, and holes. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "530" has been used to designate both gas fitting and waste tube system. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

*Specification*

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. It appears that there are numerous errors in the specification regarding the drawings rendering comprehension of the invention difficult.

*Claim Rejections - 35 USC § 112*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 31-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The connection, interrelationship, and configuration of the structural elements and their function with respect to each other are not clearly described in the specification. Part of the clarity issue may be due to the use of the same reference characters for the same elements and the use of the different reference characters to describe the same elements.

*Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 31-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,472,672 to Brennan in view of WO 98/10857 to Zuckermann et al.

Brennan discloses a method of selectively and sequentially dispensing a plurality of reagent solutions to a plurality of vials divided into first and second banks of vials and selectively purging material for the first and second banks of vials using a polymer synthesis apparatus (20) (figs. 1-7).

The polymer synthesis apparatus comprises a delivery assembly (43) for controlling delivery of liquid reagents through an array of nozzles (22) mounted on mounting blocks (37) of

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head assembly (21) in nozzle rows (40) and columns (41), which align with selected vials (26) of plate (32) within sliding plate (33) of base assembly (25) via transport mechanism (27) (figs. 1-7; col. 5, line 60-col. 7, line 16; col. 8, lines 7-35). Each bank or row of nozzle is coupled to a different liquid reagent applied in a particular polymer synthesis (col. 6, lines 49-56). For instance, the first row of nozzles may only dispense the activator tetrazole while the second row dispenses amidite thymidine (col. 6, lines 56-59). In oligonucleotide synthesis, this order of liquid reagent distribution may continue down the line for amidites adenosine, cytosine, and guanine, the auxiliary base AnyN, solvent wash/reaction solvent acetonitrile, Cap acetic anhydride, Cap N-methylimidazole, iokine, and deblockers dichloroacetic acid or trichloroacetic acid; all of which are reagents used for the synthesis of defined sequence oligonucleotides (col. 6, lines 59-66). The step of dispensing is performed in a parallel fashion since all wells within a row or bank are simultaneously addressed. The step of dispensing is performed in a serial fashion since each row or bank is separately addressed. The system permits simultaneous alignment of all the wells with all the nozzles (col. 6, lines 32-39).

Each vial contains a retaining device (84) positioned in the bottom of the vial between orifice (74) and solid support (75) for preventing the passage of the solid support through the orifice (figs. 5 and 6). The retaining device is preferably a polyethylene or glass fiber frit, which acts as a filter membrane permitting reagent solution to flow through while retaining the solid support and polymer chain grown thereon (col. 10, line 59-63).

After synthesis completion, reagent solution is purged from the vials through the orifice into drain (81) by increasing the gas pressure differential above the predetermined amount, which overcomes the capillary forces in the orifice (figs. 1, 3, 4-6; col. 10, lines 44-49).

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Subsequently, the purged reagent solutions may be drawn out of the drain through a waste tube (83), which may be coupled to a vacuum pump to create the pressure differential by forming a vacuum in the drain (figs. 1, 3, 4-6; col. 10, lines 50 and 51; col. 11, lines 55-57). Second and third waste tubes (82) are integrated with the gas flow assembly employed to flush the headspace in common chamber (31) of reagent toxins (col. 9, lines 34-66; col. 11, lines 3-6). The waste tubes also control the pressure differential in the common chamber for purging the vials (col. 10, line 50-col. 11, line 28).

Note: The ambiguous term "engaging" has been interpreted as involving, operating, or using, such that a drain is engaged with a bank of vials with a waste tube when it is put in operation for purging the contents of the vials. The ambiguous term "disengaging" has been interpreted as not involving, not operating, or not using, such that the waste tube is disengaged from the drain when it is not purging the contents of the vials. Brennan discloses that purging occurs only after the completion of the synthesis reaction, such that the drain is engaged with a bank of vials with a waste tube when purging is in progress (i.e. the waste tube is withdrawing materials from the vials). During synthesis, purging is not in progress such that the waste tube is disengaged from the drain (i.e. waste tube is not active).

Brennan discloses engaging a drain with all banks of vials. Brennan fails to disclose engaging a drain with a certain bank of vials. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus of Brennan to engage a drain with a certain bank of vials since it is well suited for solid phase synthesis chemistry reactions such as polypeptides, peptoids, and polynucleotides in which a sequence of reaction steps are carried out in parallel using a plurality of reaction vessels

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as taught by Zuckermann et al. (abstract; figs. 2 and 4; page 3, lines 12-27; page 6, lines 16-19 and 26-28; col. 8, lines 7-9; col. 12, lines 13-15).

11. Alternatively, claims 31-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,472,672 to Brennan in view of WO 98/10857 to Zuckermann et al. as applied to the claims above, and further in view of U.S. Patent No. 5,424,038 to Benz et al.

Brennan in view of Zuckermann et al. fail to disclose "physical connecting" the drain with a bank of vials and "physically disconnecting" the waste tube from the drain. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus of Brennan in view of Zuckermann et al. to "physically connect" the drain with a bank of vials for purging the system and "physically disconnect" the waste tube from the drain since the configuration allows serial assays without personnel for exchanging and washing the vials and flexible liquid treatment times and capacity as taught by Benz et al. (col. 1, lines 48-61; col. 2, lines 42-49).

### *Conclusion*

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. They include one or more limitations in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan  
Examiner  
Art Unit 1743

eq

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700